

K121498
DEC 14 2012

510(k) Summary of Safety and Effectiveness for Update to PercuNav

I. Manufacturer/Owner

Manufacturer's Name

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II. Contact Person

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III. Propriety Name/Classification Name

Propriety Name:	PercuNav
Common Name:	Computer assisted, image-guided surgery system
Classification Name:	Computed Tomography X-ray System Class II as described in 21 CFR 892.1750
Product Code:	JAK

IV. Date Prepared

November 13, 2012

V. Device Description

The PercuNav image fusion and navigation feature for the iU22 Diagnostic Ultrasound System is supplied as an on-cart product that is packaged and installed much like a peripheral on the iU22 Diagnostic Ultrasound, similar to a third party VCR which can be placed on the ultrasound cart.

PercuNav computer assisted technology provides image guided intervention and diagnostic information which guides interventional instrumentation to targets that has

been defined by the physician. The target can be indicated either pre-procedurally or intra-procedurally using images or relative to an indicated position on the patient. As a diagnostic system, it combines pre-procedural and intra-procedural imaging to assist in locating areas of interest detected on one set of images on the other. The system provides fusion between different modalities. Different imaging modalities such as CT, Ultrasound, PET, MR, and Rotational Fluoroscopy may be fused in various combinations, for example CT with MR, CT with Ultrasound, PET/CT with ultrasound, MR with ultrasound, etc.

When used as a navigation aid, it also transforms two and three-dimensional patient images (scan sets), derived from for example, Computed Tomography (CT), Magnetic Resonance Imaging (MR), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Ultrasound (US), Rotational Fluoroscopy, etc. into dynamic representations on which a medical instrument can be navigated. The system performs spatial mapping from one image space to another image space or from image space to physical space ("registration") allowing the physician to correlate scan sets with each other and to the patient. The system facilitates minimally invasive interventional procedures. Like other commercially available image guided surgery systems, the PercuNav also offers computer assisted image-free navigation using the same instrumentation. In image-free mode the proximity of an interventional device is displayed relative to another device.

Images used by the PercuNav can include archived image data from a CD, PACS, etc., and live images from an imaging device such as ultrasound, etc. The system can also be used without the use of image data (image-free mode) when appropriate for the procedure being performed.

The PercuNav system consists of an Electromagnetic Measurement System (EMMS) (including a Field Generator and System Control Unit), a System Unit, Field generator stand, PercuNav software, Tool Connection Unit (TCU), and various instrumentation devices. The PercuNav System Unit and the PercuNav software interact with the keyboard, touch-screens, trackball, and visual display of the iU22 Diagnostic Ultrasound System to display and interact with images and data on the system monitor(s).

Targeted use areas for PercuNav include hospital operating rooms, outpatient surgery centers, ultrasound, CT and other scanner suites, and procedure rooms.

VI. Purpose of Submission

The purpose of this premarket notification is to seek clearance for an update to the currently approved Indications for Use cleared for the PercuNav predicate device. The PercuNav System, originally named "Abaris" (K053610, cleared April 16, 2006) is currently marketed by Philips Healthcare. The manufacturer Traxtal Inc. was acquired by Philips Electronics and is now Philips Healthcare, a division of Philips Electronics Ltd.

VII. Description of Device Modification

This submission provides new indications that are substantially equivalent to the named predicate device indications statement. The proposed indication for use is essentially identical to the currently cleared indications, with the exception of reference to example procedures where the PercuNav System can be used. As required by risk analysis, all verification and validation activities were performed by designated individual(s) and the results demonstrated substantial equivalence to the predicate device.

VIII. Indications for Use

PercuNav is a stereotaxic accessory for Computed Tomography (CT), Magnetic Resonance (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Rotational Fluoroscopy, Endoscopy, and other imaging systems. CT, Ultrasound, PET, MR, and Rotational Fluoroscopy may be fused in various combinations, such as CT with MR, MR with ultrasound, etc. It may include instrumentation to display the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account patient movement. This is intended for treatment planning and guidance for clinical, interventional, and/or diagnostic procedures. The device also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device.

The device is intended to be used in interventional and diagnostic procedures in a clinical setting. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another.

Example procedures include, but are not limited to:

- Image fusion for diagnostic clinical examinations and procedures
- Soft tissue biopsies (liver, lung, kidney, breast, pancreas, bladder, adrenal glands, lymph node, mesentery, etc.)
- Soft tissue ablation (liver, kidney, breast, pancreas, lung, etc.)
- Bone ablations
- Bone biopsies
- Nerve Blocks & Pain Management
- Drainage placements
- Hydrodissections
- Bladder Stimulation
- Fiducial placements
- Tumor resections
- Sinus procedures
- Intranasal procedures
- Transphenoidal procedures

IX. Substantial Equivalence

The technological characteristics of the proposed PercuNav device are similar to the cleared predicate device with exception of revisions to the system software which has improved image fusion and navigation workflow and added features which enhanced physician usability. It is important to note that all updates made to the PercuNav software have not impacted safety or effectiveness. This update to the PercuNav system is substantially equivalent to the FDA cleared frameless stereotaxic system, predicate PercuNav (a.k.a. Abaris) K053610. As required by risk analysis, all verification and validation activities were performed by designated individual(s) and the results demonstrated substantial equivalence.

The device labeling contains instructions for use which is substantially equivalent to the predicate device. It includes indications for use, cautions, contraindications, warnings, and planning guidance. This information assures safe and effective use of the device.

X. Testing and Performance Data

Testing for the PercuNav system was performed to ensure that functional requirements have been met, and that core functions execute as expected. Safety and Effectiveness of the PercuNav system has been established through bench testing and non-clinical performance data also known as Surgical Simulation Testing. Results from System Testing and Surgical Simulation testing demonstrate that the PercuNav system is safe and effective for its intended use.

System Testing

Product requirements are decomposed into test cases and variations, consisting of conditions and expected results. Each case set is associated with a specific requirement and is grouped according to functional characteristics. The Software Validation Test Plan (SVTP) identifies all variations, including input and expected results (outputs), test setup conditions (environmental needs), requirements, variations tested, and procedural steps taken to execute the test case. The test case results summary demonstrate that the device satisfies all performance and functional requirements.

Surgical simulation

A real-world simulation of a guided surgical procedure to determine the accuracy of the PercuNav system using a control measurement gauge. It is also used to determine if the system works as intended in a simulated surgical environment. The system is validated using a phantom based simulation that is designed to determine the error in the system by determining a value of "Euclidian System Error". The Euclidian System Error is the "Target Registration Error" (TRE) commonly used for accuracy assessment in image guided surgery.

TRE is a well established method of determining accuracy of image guided procedures, and has been use in a number of studies, particularly rigorous engineering evaluations (Maurer, Maciunas and Fitzpatrick 1998). TRE is defined as the error discrepancy between PercuNav and ground truth position as estimated for

example from a CT confirmation scan. TRE defines the error of misrepresentation of the tracked device location reported by the system and its real location and is the superposition of registration errors, motion artifacts, position sensor error etc. In the field of image guided intervention, TRE is considered by most researchers as the most clinically relevant measure of error since it is a direct measure of the full system accuracy.

The surgical simulation protocol and expected results (e.g. accuracy) is detailed in the Surgical Simulation Test Case Protocol. All instrumentation and accessories provided with the PercuNav system are subjected to the Surgical Simulation Test Case Protocol. The results of the surgical simulation are documented and referred to in a Verification and Validation Report for the PercuNav system.

System testing to date shows that all accuracy targets for the PercuNav system have been met and the system is safe and effective for its intended use. The completed tests were conducted to ensure that the changes to the proposed device did not introduce any new issues of safety or effectiveness from our legally marketed predicate device - K053610.

XI. Conclusion

The proposed indication for use is essentially identical to the currently cleared indications, with the exception of reference to example procedures where the PercuNav System, formerly known as Abaris, can be used. Safety and effectiveness of the example procedures have been established through clinical experience and preclinical testing including system design bench testing. Results of the verification and validation activities for the PercuNav system confirm that the system performed as intended, is safe and effective, and is substantially equivalent to the currently marketed predicate device [K053610].



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 14, 2012

Philips Healthcare
% Ms. Tara MacKinnon
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49 Spandina Avenue, Suite 310
Toronto, Ontario, M5V 2J1
CANADA

Re: K121498
Trade/Device Name: PercuNav
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 12, 2012
Received: November 14, 2012

Dear Ms. MacKinnon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Sean M. Boyd

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

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- Bone ablation
- Bone biopsies
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- Drainage placements
- Hydrodissections
- Bladder Stimulation
- Fiducial placements
- Tumor resections
- Sinus procedures
- Intranasal procedures
- Transphenoidal procedures

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Sean M. Boyd

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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